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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,087	11/06/2000	Carl H. June	RPI-034CPCN	8859

959 7590 02/24/2004

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,087	JUNE ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 32-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/21/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/17/03 has been entered.

Claims 1 and 39 have been amended, and claims 1, and 32-46 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e.,

continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

The specification is objected to because page 1, line 12 contains blank space. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are vague and indefinite because of claim recitation, "mature T cells". In 9/17/03 response, applicants indicated that the specification recites the term in page 6, line 30", and explain that a mature T cell is a terminally differentiated T cell that migrates out of the thymus and circulates in the blood stream, or (Response, page 6). This definition agrees with the original disclosure which recites mature T cells following immature T cells in a markush group, and meets the plain meaning for the term, i.e. terminally differentiated as oppose to undifferentiated (stem and progenitor cells), thus is acceptable. However, applicants later appear to argue that transformed T cells are not considered as mature T cells (Response, page 8). This is confusing because a

transformed mature T cell is still a mature T cell, would not change to an immature T cell. Particularly considering claim 37 is drawn to treating an HIV virus infected T cells (transformed), the exclusion would be contradict the claims. Thus, in view of applicants' argument, the metes and bounds of the claims are unclear. Further, the specification fails to specifically redefine the term, and if applicants intend to exclude a transformed mature T cell from the claimed term, it would represent a departure from the term as originally recited, thus, would introduce new matter to the disclosure.

Claims are vague and indefinite because of claim recitation, a "submitogenic amount of an anti-CD3 antibody". However, except disclosing a specific dose in a working example, the specification fails to teach what dosing range is considered as submitogenic, what dosing range the term embraces or excludes, thus the metes and bounds of the claims are unclear. In 9/17/03 response, applicants indicated that the specification teaches a specific amount of anti-CD3 antibody (1 μm/ml) in page 33, lines 35-39, and recites "submitogenic doses of anti-CD3" in page 43, line 17. However, it is noted in U.S. patent 6,352,694 by applicants, June et al teach the dosing range of anti-CD3 antibody for inducing a population of T cells to proliferate, for example, in column 31, line 33, they teach, "WITH OKT3, THE OPTIMAL CONCENTRATION WAS DETERMINED TO BE TYPICALLY IN THE RANGE OF 0.1 TO 10 MICROGRAMS PER MILLILITER", wherein the **specified *submitogenic*** amount in the instant application is at exact mid-point of the dosing range that induces T cell proliferation. Since the same dose would induce T cell proliferation, and is submitogenic, it is further unclear, what the claimed term embraces or excludes, thus, the metes and bounds of the claims cannot be readily determined.

For the sake of a compact prosecution, the dosing range of 0.1 to 10 mg/ml would be used as the standard for the submitogenic amount.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 32-46 stand rejected and the rejection has been modified in view of the amendment and upon further consideration under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and following.

In 9/17//03 paper, applicants indicated that claims have been amended to recite, "mature", and "submitogenic amount". Applicants argue that Kwon et al refers to AICD as in immature T cells, hybridomas and transformed cell lines, and use high dose of anti-CD3 antibody, not a submitogenic amount.

In response, it is noted that *Kwon et al* do use mature peripheral T cells (PBMC, column 20, lines 53-55), not immature T cells, for contacting of anti-CD3 and anti-CD28 antibodies. On the other hand, the claimed invention does not have limitation on times of exposure, thus encompasses the condition taught by *Kwon et al*, i.e. repeated exposure to anti-CD3 and anti-CD28. It is also noted *Kwon et al* do recite a high dose of anti-CD3, however, the amount used in contacting PBMC was 1 μg/ml soluble anti-CD3 mAb (column 17, line 31), apparently the term "high" is a relative one, thus they did use

submitogenic amount as defined by the applicants 9/17/03 response. Accordingly, the arguments are not persuasive.

Applicants then argue that example 6 of the instant application describes experiments performed on Jurkat cells, which are of a transformed cell line and subject to AICD, and examples 1-5 utilize primary mature T cells, that are not subject to AICD.

In response, it is noted that Jurkat cells are terminally differentiated mature T cells though transformed, and have been widely used in the art for studying characteristics of T cells. The brief recitation of "mature" T cells in the original disclosure appears to be used as contrast to immature and it does not exclude Jurkat cells. It is additionally noted that in examples one through six, the original disclosure refers to cells used as "resting" and "activated", either they are primary or Jurkat line, accordingly, it appears that not only the Jurkat cells are subject to AICD but the regular mature T cells are also subject to AICD.

Applicants then argue that *Lenardo* teach a specific effect of IL-2 exposure of T cells in vitro with respect to prior antigen exposure, does not say that instant claimed invention will not work. In response, it is noted the invention as claimed encompass the situation taught by Lenardo et al, thus the claims are not fully enabled with the scope.

With respect to the superantigens, Applicants again argue that cited references discussing specific situations, do not say that the present invention is not enabled. In response, since the claims encompass the said specific situations, they are not fully enabled with the scope.

With respect to the therapeutic aspect of the invention, applicants argue that the art is not as unpredictable as those cited references, arguing details of each reference, and concluded that the teaching of the references have no bearing on the instant claims.

The arguments are not persuasive because it was noted in the previous Office actions that all of the art of record teach simplified *in vitro* effect, wherein it is possible to separately look at the effect of a certain agent, or a combination of a few agents, whereas under *in vivo* situation, many other cell surface receptors, apoptotic associated molecules, and cytokines act in concert to determine the overall fate of a cell. The cited numerous references teach different aspects of an *in vitro* effect, which various depending on a particular cell type and a particular treatment. Once these treated cells were reintroduced into the subject, the fate of the T cells, influenced by many other factors in the blood stream, can not be predictably determined by the *in vitro* data. Otherwise, the cited art of record would have reasonably anticipated instantly claimed invention. For example, T cells function as different subtypes, once the resting T cells activated, they may be helper, suppressor, cytotoxic etc., each subtype respond to particular activators such as an antigen or a cytokine. The art of record is silent and the specification fails to teach the circumstance necessary to introduce these generalized mature T cells into a subject, or once they are activated, or differentiated, the ex vivo observed protective effect would remain, thus, the specification fails to provide an enabling disclosure to guide the practice of the invention. Applicants are reminded that 35 U.S.C. § 112 requires that the scope of the claims must bear a reasonable

correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In re Fisher, 166 USPQ 18, 24 (CCPA 1970). In the instant case, the specification provides **no** evidence with respect to how the treated T cells would behave in vivo, the functionality and pharmacokinetics of these T cells, and conditions for using such cells. The Federal Circuit has stated that:

> a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure** of any specific starting material **or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art**. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

Claims 1 and 32-46 are newly rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. These claims read on using any combination of two agents as recited in claims 1 and 39, for example a combination of CD28 ligand and an ionomycin. However, the specification and the numerous cited art of record (see sections following) have shown the necessary presence of or pre-exposure to the anti-CD3 antibody such as those shown in figure 2 and experiment 2. The specification provides no evidence that in the absence of the anti-CD3, any other combination would result in T cell protection. In fact, the specification shows that anti-

CD28 could enhance bcl-x expression caused by T cell exposure to anti-CD3 (fig. 3), but anti-CD28 alone did not induce detectable Bcl-X_L as shown in figure 5. Since the specification teaches that the increased Bcl-X_L is the key to T cell survival, in the absence of evidence to the contrary, the invention as claimed do not appear to be enabled.

Accordingly, for reasons of record and set forth supra, the specification fails to meet the statutory enablement requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 34, 37, and 38 stand and newly rejected and claims 32, 33, and 35 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *June et al* (US 6,352,694, and 6,534,055).

The applied reference has at least one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e)

might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 32, 33, 35 should also be included in the rejection because *June et al* teach a method comprising contacting T cells *in vitro* with an anti-CD3 antibody (e.g. step a of claims 1 and 17 of the cited '694 patent), and an anti-CD28 antibody (step b of claim 1 of the cited '694 patent) or an anti-CD2 antibody, preferably T11.1 (column 5, line 65-column 6, lines 12) or PHA (column 3, line 20), wherein the anti-CD3 is OKT3 (column 5, line 62).

The teachings of '694 patent as detailed above and in the previous Office action paper #11 are also disclosed in the newly cited '055 patent.

In 9/17/03 response, applicants argue that apoptosis and proliferation is not necessarily coincide, and applicants have identified a function of anti-CD3 in T cells which is independent of its proliferative activity, and that June et al do not teach a submitogenic amount of anti-CD3 antibody.

The arguments have been fully considered, but they are not persuasive for reasons of record and following.

First, it is noted that although June et al do not use the term "submitogenic", they do teach the dosing range of anti-CD3 antibody for inducing a population of T cells to proliferate. For example, in column 31, line 33, they teach, "With OKT3, the optimal concentration was determined to be typically in the range of 0.1 to 10 micrograms per

milliliter", wherein the specified dose in the instant application is 1 μm/ml, at exact mid-point of the taught dosing range, thus, the teaching of June et al meet claim limitation.

Second, the method step of cited patent meets claim limitation. Although the effect of increasing Bcl-X was not disclosed in the cited patents, as indicated in the previous action, that merely discovering and claiming a *new benefit* to an old process *cannot* render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Accordingly, the cited patents anticipate the instant claims.

Claims 1, 35, 36, 37, and 38 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Groux et al* (J Exp Med 1992;175:331-340).

Groux et al teach a method comprising contacting human matured T cells with an anti-CD3 antibody at a submitogenic amount (1 μg/ml, 2nd paragraph, left column, page 332), plus anti-CD28, PHA, PWA, and superantigen SEB (figures 1 & 2), wherein the T cells are from either HIV seropositive (infected) or seronegative patients. *Groux et al* go on to teach that anti-CD28 prevented T cell apoptosis (e.g. abstract). Accordingly, *Groux et al* anticipate instant claims.

Claims 1, 32, and 38 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Wolf et al* (Eur J Immunol 1994;24:1410-17).

Wolf et al teach a method comprising contacting human matured resting T cells with an anti-CD3 antibody (OKT3) at a submitogenic amount (e.g abstract and fig. 1), plus anti-CD28 or anti-CD2 (table 2 and figure 3), wherein the combined administration of anti-CD3 and one of the co-stimulatory molecule anti-CD28 or anti-CD2 could prevent anti-CD3 induced T cell anergy. *Wolf et al* go on to teach that anti-CD3 induced T cell anergy is associated with increased cell death (e.g. § 3.2, page 1412) and prevented by the co-stimulatory molecule (§ 3.4, page 1414). Accordingly, *Wolf et al* anticipate instant claims.

Claims 1, 32 and 38 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Lederman et al* (US 6,610,294).

Lederman et al teach a method comprising contacting mature human T cells (column 34, lines 46-55) with anti-CD3 and PBD (column 27, lines 56-59), wherein the anti-CD3 is OKT3 and coated on a culture surface, although *Lederman et al* do not specify the amount used, considering the common practice in the art using a dosing range of 0.1-10 μg/ml for coating surface, and 1 μg/ml for stimulating T cells as evidenced by *Groux et al*, and *June et al*, the amount is assumed to be submitogenic in the absence of evidence to the contrary. Accordingly, *Lederman et al* anticipate instant claims.

Claims 1, 32-35, 37, and 38 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Gary et al* (US 5,883,223).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Gary et al teach a method comprising contacting T cells *in vitro* with an anti-CD3 (OKT3, column 4, line 50) at a submitogenic amount (column 20, line 55) and an anti-CD28 antibody (example 1) or an anti-CD2 antibody, preferably T11.1 (column 5, line 65-column 6, lines 12), or IL-2 and PHA (fig. 1), or B7-1 and B7-2 (column 6, lines 26-27), wherein the T cells could be obtained from HIV infected patients (fig. 15). Accordingly, *Gary et al* anticipate instant claims.

Claims 1, 32-38 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Thompson et al* (US 6,685,941).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Thompson et al teach a method comprising contacting T cells *in vitro* with an anti-CD3 (OKT3) at a submitogenic amount and anti-CD28 antibody (e.g table 13) or IL-2 and PHA (table 3), or B7-1 and B7-2, or superantigen SEB (fig. 16), wherein the T cells could be obtained from HIV infected patients. Accordingly, *Thompson et al* anticipate instant claims.

Claims 1, and 32-38 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

This application has a different inventive entity as that of US Patent 5, 883,223; 6,352,694; 6,534,055; and 6,685,941 but the subject matter is anticipated by the cited patents, it is unclear with regard to who is the real inventor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The prior rejection of claims 1, 34, and 38 under 35 U.S.C. 103(a) as being unpatentable over *Lenardo* (US 6,083,503), and in view of *Roberts* (US 5,686,281), is withdrawn because *Lenardo et al* teach away from the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 32-35, 37, and 38 stand or are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15-19, 31, and 32 of U.S. Patent No. 6,352,694.

Applicants reiterated the arguments as stated under § 102 (e), and pointed out that the amended claims recite, "submitogenic amount".

In response, for the same reasons stated above, and because the submitogenic amount is fully disclosed in the cited patent, the rejection stands.

Claims 1, 32-35, and 38 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,534,055.

The reference patent qualifies as prior art under this provision because there is at least one common inventor and no common assignee between the instant application and the cited patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the present application and claims of the cited patent are each drawn to a method comprising the steps of contacting the T cell with two agents selected from the group consisting of anti-CD3 antibody, anti-CD28 antibody, a CD28 ligand, and IL-2.

The processes of the present application and the cited patent differ one from the other in the preamble recitations, however, the recitations "for expanding a population of T cells" or "for preparing a renewable source of T cells" in the cited patent or "for protecting a T cell from cell death" in the present application are obvious variants, i.e. maintaining a T cell population in culture. Further, the preamble recitations have not been given patentable weight because they merely recite an intended use of the process. Please note that intended use limitations bear little weight on the determination of novelty of the invention. It is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Accordingly, the inventions as claimed are co-extensive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
February 20, 2004